

connected to a corresponding fastener or fixing means **330** on the proximal cuff **110** of ankle foot orthosis section **310** (FIGS. **13-15**). The corresponding fastener or fixing means **330** may be located at or near a side rear of the proximal cuff. The fastener or fixing means **330** may be any appropriate device and may include, but is not limited to, a bolt, rivet, screw, clasp, and the like. The placement of the fastener or fixing means **330** may help in providing the level of hamstring assist that is required for a patient or user.

[0079] A manual connection allows a user or patient to use the at least one stretchable band **325** or to decide not to use the at least one stretchable band **325**, depending on the activity, environment, and/or injury. Thus, for example, if there are two stretchable bands on each side of the knee orthosis section **305**, a patient may manually connect just one pair of stretchable bands to the ankle foot orthosis section **310** (e.g., FIG. **13**).

[0080] This embodiment of the knee ankle foot orthosis acts like an artificial hamstring and, in particular, may be helpful to individuals with hamstring injuries or sciatic nerve problems. This version of the knee ankle foot orthosis also allows for backward movement, thereby allowing for a controlled normal type of running.

J. Alignable and Non-Alignable Versions of Orthosis

[0081] With reference now to FIGS. **16a-17**, in specific embodiments, the exoskeletal orthosis may have an alignable (FIGS. **16a-16b**) or a non-alignable (FIG. **17**) configuration. Both configurations may be fixed or modular.

[0082] The alignable or non-alignable exoskeletal orthosis comprise a proximal cuff; an ankle section/footplate; and at least one posterior strut connecting a rear of the proximal cuff to a rear of the ankle section/footplate. In the alignable configuration, the at least one posterior strut (e.g., dual posterior struts) is connected to at least one of the ankle/footplate or the posterior cuff via a bolt mechanism **400**, as shown in FIGS. **16a-16b**.

[0083] In specific embodiments, the bolt mechanism **400** may comprise at least one threaded bolt **405**, a washer **410**, and two opposing discs **415**, **420**. Each of the two opposing discs **415**, **420** may have reciprocal curved surfaces (as shown in FIG. **16b**) for receiving a posterior strut.

[0084] Between a bottom opposing disc **420** and a surface of the ankle/footplate **140**, at least one angled wedge **425** may be placed to allow for anteroposterior or lengthwise alignment changes or mediolateral or crosswise alignment changes. The angled wedge **425** may have, for example, about 1-8° rise or incline. A threaded laminate plate **430** for tightening the bolt mechanism may be placed below a surface of the ankle/footplate. In specific embodiments, the laminate plate **430** may have a thickness of 0.2 inches to 0.5 inches (5 mm to 12.7 mm), for example, 0.25 inches to 0.4 inches (6 mm to 10 mm).

[0085] FIG. **17** shows a non-alignable configuration in which the at least one posterior strut **130** (e.g., a dual strut configuration) is fixed onto an ankle/footplate **140** and a proximal cuff **110**, for example via upper and lower mounting plates **440a**, **440b** respectively. The upper and lower mounting plates **440a**, **440b** each have moldable flaps or wings **450**, extending from the sides thereof. The moldable flaps or wings **450** may comprise a moldable metal, such as a wire cage or moldable metal band. The moldable flaps or wings **450** allow

for contouring and securing the mounting plates and at least one posterior strut to the proximal cuff **110** and/or ankle/footplate **140**.

K. Uses

[0086] The exoskeletal orthosis is a viable alternative to amputation despite severe impairment of the leg. In addition, the exoskeletal orthosis may allow at least one of: 1) a more normal walking or running pattern for those with severe injury to the leg, ankle, and/or foot that results in decreased ankle range of motion or increased pain; 2) those with an isolated peroneal neuropathy to run; 3) those with tibial neuropathy to walk and run; or 4) increased agility (stepping forward, backward, side-to-side) despite stated physical impairments. The orthosis also promotes use and subsequent strengthening of the quadriceps muscle during everyday activities. The orthosis may also be used for spinal cord injuries in which there is weakness at the ankle and at least 4 out of 5 strength in the knee.

[0087] The exoskeletal orthosis of the present invention may be modified to allow safer and more normalized gait pattern during the early postoperative period after leg/foot/ankle surgery instead of the CAM boot (a 'walking boot') The orthosis may also be used as a pediatric device for those with cerebral palsy who have ankle plantarflexion weakness associated with Achilles lengthening procedures and hamstring weakness.

[0088] Although the present invention has been described in terms of particular exemplary and alternative embodiments, it is not limited to those embodiments. Alternative embodiments, examples, and modifications which would still be encompassed by the invention may be made by those skilled in the art, particularly in light of the foregoing teachings.

[0089] Those skilled in the art will appreciate that various adaptations and modifications of the exemplary and alternative embodiments described above can be configured without departing from the scope and spirit of the invention. Therefore, it is to be understood that, within the scope of the appended claims, the invention may be practiced other than as specifically described herein.

What is claimed is:

1. An exoskeletal orthosis, comprising:
a proximal cuff;
an ankle section/footplate; and
a single posterior strut connecting a rear of the proximal cuff to a rear of the ankle section/footplate.
2. An orthosis according to claim 1, wherein the proximal cuff further comprises a hinge along an upper edge of the cuff, thereby allowing the proximal cuff to open.
3. An orthosis according to claim 1, wherein a top of the single posterior strut is incorporated into a rear of the proximal cuff and a bottom of the posterior strut is incorporated into a rear of the ankle section/footplate.
4. An orthosis according to claim 1, wherein the proximal cuff comprises a reinforced carbon fiber composition.
5. An orthosis according to claim 1, wherein the single posterior strut has a tubular or cylindrical shape.
6. An orthosis according to claim 1, wherein the at least one posterior strut has a length of about 5 inches to about 13 inches (about 15.2 cm to about 33 cm).
7. An orthosis according to claim 1, wherein the ankle section/footplate comprises a supramalleolar ankle section.